ABIOMED
Recovering hearts. Saving lives.

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June 21, 2019

Seema Verma, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1716-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, Maryland 21244-1850

Re: CMS-1716-P – Fiscal Year 2020 Inpatient Prospective Payment Systems for Acute Care Hospitals – Coding and MS-DRG Classification For Heart Assist Devices, MS-DRG 215

Dear Administrator Verma:

Abiomed, Inc. appreciates the opportunity to comment on the FY 2020 Hospital Inpatient Prospective Payment Systems (IPPS) Proposed Rule, published on May 3, 2019, which reduces payments for heart-assist devices by a larger percentage than any other MS-DRG.[1] Abiomed is the developer and provider of Impella, which provides circulatory support, enabling the heart to rest and recover after a life-threatening event, and is the only FDA PMA approved percutaneous device for heart attack or during the treatment of coronary artery disease in severe heart failure.
We are concerned that the Proposed Rule, if finalized, would result in a tiered payment system for heart assistance devices, resulting in significant underpayment of hospitals for life-saving and resource-intensive procedures for FDA PMA heart assist indications.

We are writing to comment in support of policies that will increase beneficiary access for all clinically validated heart assist devices. In particular, the Proposed Rule would decrease the relative weight for Other Heart Assist System Implant (MS-DRG 215), the primary MS-DRG for Impella by approximately 30%. Another heart assist device, extracorporeal membrane oxygenation (ECMO), has experienced significant underpayments for peripheral procedures in FY 2019. Abiomed supports the clinical use of ECMO, and we agree with CMS that the current MS-DRG assignments for peripheral ECMO procedures should be reassigned to MS-DRGs that more appropriately reflect the costs and resources for these procedures. However, the Proposed Rule would temporarily return back to the old MS-DRG structure acknowledged to be inaccurate in payment. This would create a tiered system of payment that would not uniformly reflect the costs and resources of all heart assist devices. We are offering a recommendation that would create a **permanent solution** to all short term heart assist devices for all providers.

We recommend that CMS extend the "hold harmless" from the FY 2019 IPPS Final Rule to maintain the FY 2018 relative weight for MS-DRG 215 to allow for new AHA/CMS coding guidance and new FDA indications to be represented in the claims data. CMS should also increase the payment for peripheral

[1] CMS, Medicare Program: Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and Long-Term Care Hospital Prospective Payment Systems and Proposed Policy Changes and Fiscal Year 2020 Rates, etc.., Proposed Rule, 84 Fed. Reg. 19158 (May 3, 2019).

ECMO cases that do not require an open chest procedure by assigning the new intraoperative ICD-10 PCS codes for peripheral ECMO to MS-DRG 215 and evaluate if the combination of multiple cardiac assist devices are better aligned to MS-DRGs 001/002. These newly issued codes provide a path for aligning ECMO codes to resource consumption that was not available when the Proposed Rule was released. CMS should keep central ECMO procedures in MS-DRG 003.

Clinical Background on Heart Assist Devices

Abiomed is a provider of heart assist devices referred to as percutaneous ventricular assist devices, (PVADs) that provide circulatory support, enabling the heart to rest and recover after a life-threatening event such as a heart attack or during the treatment of coronary artery disease in severe heart failure. Abiomed's Impella is FDA-approved for the treatment of heart attacks that deteriorate into cardiogenic shock, a condition in which end organs such as the liver and kidneys begin to shut down due to limited perfusion. Impella is also approved for stabilization during high-risk coronary procedures for patients who are often refused for surgical procedures, of which age is a common risk factor. The goal of treatment is to maintain native heart function and reduce long-term heart failure post heart attack, which is a contributor to poor quality of life and increased healthcare resources for the elderly.

Impella has demonstrated reduction in heart failure, improvement in heart function, and reduction in readmission in both Randomized Control Trials and large FDA post approval registries. In February 2018, FDA approved an additional indication for Impella heart pumps, for the treatment of cardiomyopathy with cardiogenic shock. Studies demonstrate that Impella improves survival rates of patients with cardiogenic shock and improves native heart recovery. Patients receiving PVADs primarily require intensive care and additional time in the hospital reflected in MS-DRG 215 (Other Heart Assist System Implant).

ECMO is a bypass technique that supports patients with reversible cardiopulmonary insufficiency refractory to conventional management. The FDA has not approved a medical device with labeling demonstrating safety and efficacy for ECMO. Although ECMO was historically only performed through open-chest procedures on pediatric patients, today hospitals are increasingly performing peripheral ECMO procedures with multiple cannulation techniques. Different ECMO approaches provide different targeted clinical support to patients with varying levels of invasiveness. Abiomed supports the use of ECMO for patients needing oxygenation.

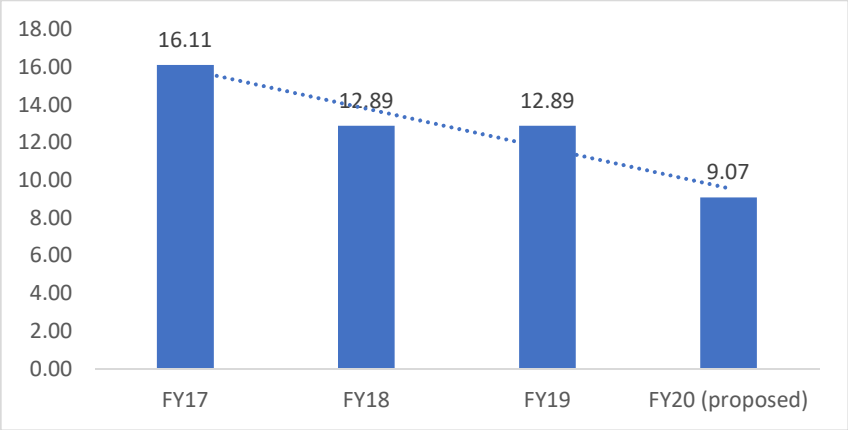
FY 2020 Proposed Rule Significantly Affects Payment for Heart Assist Devices

The FY 2020 Proposed Rule would, if finalized, result in cuts in payments for heart assist device procedures and create a tiered payment system for heart assist devices that does not uniformly reflect the cost and resources of these devices. The Proposed Rule would result in a significant reduction in payment for MS-DRG 215. CMS also amends MS-DRG assignments for peripheral ECMO procedures to fix underpayments for those procedures stemming from changes in the FY 2019 Final Rule. While we agree that increased payments for peripheral ECMO are necessary, the Proposed Rule addresses payments for peripheral ECMO by proposing to temporarily move all ECMO codes to MS-DRG 003, which will result significant overpayments for these procedures. We recommend that CMS instead adopt a permanent solution to align MS-DRG assignment for all heart assist devices with the appropriate costs and resources.

a. Unprecedented Payment Cuts to MS-DRG 215 Due to Claims Data, Unique Data and Timing Issue

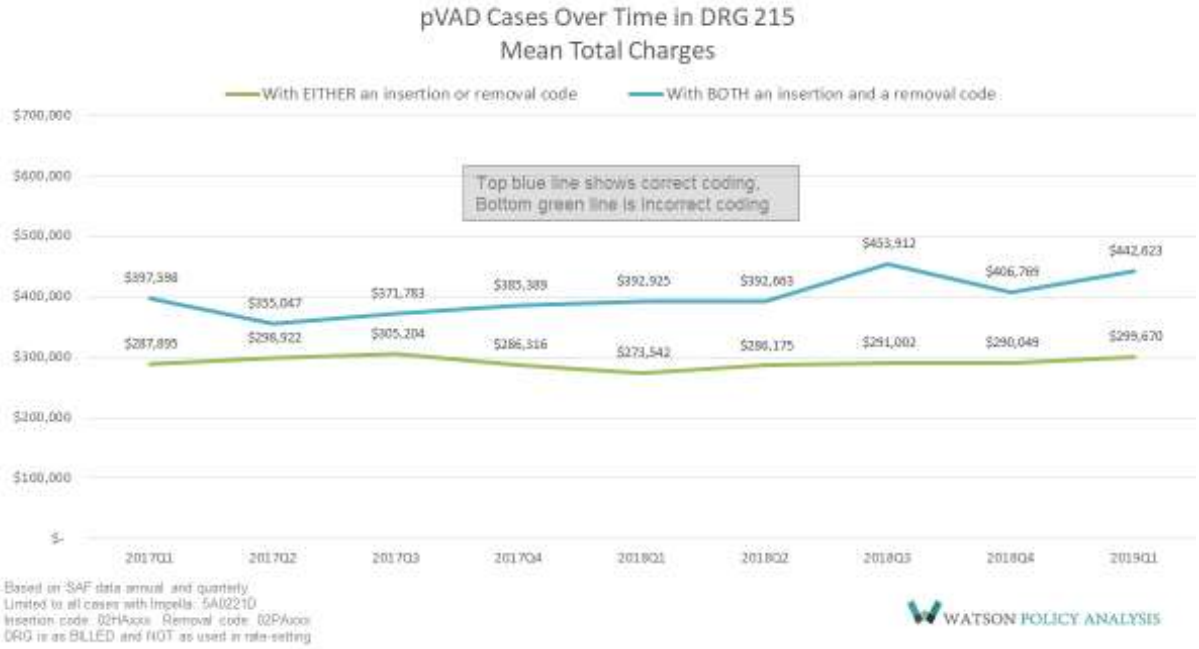
In the FY 2020 Proposed Rule, MS-DRG 215 once again experiences the largest decrease of any MS-DRG. If finalized, the relative weight for MS-DRG 215 will be reduced by over 29%. **This is the largest**

<u>decrease of any MS-DRG at a time of FDA approvals and new studies showing first increase in survival in 20 years.</u> This is the largest decrease of any MS-DRG over a three-year period.



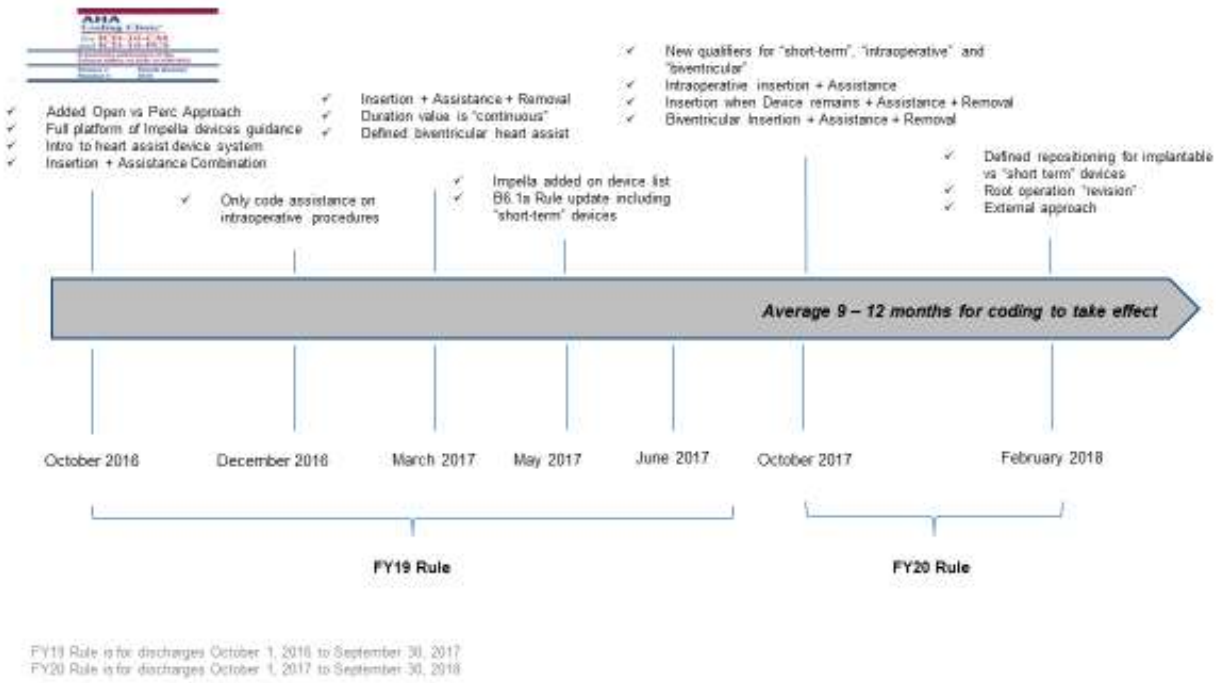
The proposed cut to the relative weight of MS-DRG 215 will result in significant underpayment to hospitals treating the highest-acuity Medicare heart failure patients, such as those suffering from heart attacks leading to cardiogenic shock and heart failure patients being treated with percutaneous coronary intervention. In addition, we believe this will limit access to care for newly FDA approved indications for critical heart pumps.

This decrease is not the subject of any specific policy change in the Proposed Rule. Instead, this dramatic decrease is the result of a unique situation where there have been 13 recent coding changes in a compressed period, along with new FDA indication, neither of which are yet reflected in the data. The relative weight for MS-DRG 215 is still impacted by this unique situation with claims data not accurately reflecting the costs of these procedures.



In the past three years, the American Hospital Association has made 13 official changes to its guidance for the appropriate coding for Impella devices. In October 2017, AHA adopted new coding guidance for the use of an insertion code in all heart assist insertion cases. The coding change directly correlates to the

CMS ICD-10-PCS B6.1a rule update for FY 2018, which allows providers to use an insertion code for certain devices where the device is used for a brief duration during the procedure or inpatient stay. In addition, the term "short-term" was added to the definition of heart assist devices which required additional coding clarification later in The Coding Clinic. These changes in coding guidance are still not reflected in the claims data making up the relative weights in the FY 2020 Proposed Rule.[2] Moreover, the conflicting nature of many of these changes has made it difficult for providers to accurately code for these procedures or keep current with the updates in guidance, therefore hospitals have not updated their charge master for new Impella codes. As a result, 68% of claims for Impella procedures did not have a charge for Impella in Revenue Center 278 (other implants). Many hospitals are not charging for the device at all. These coding changes have come at the same time as Impella has been approved for new FDA PMA indications.

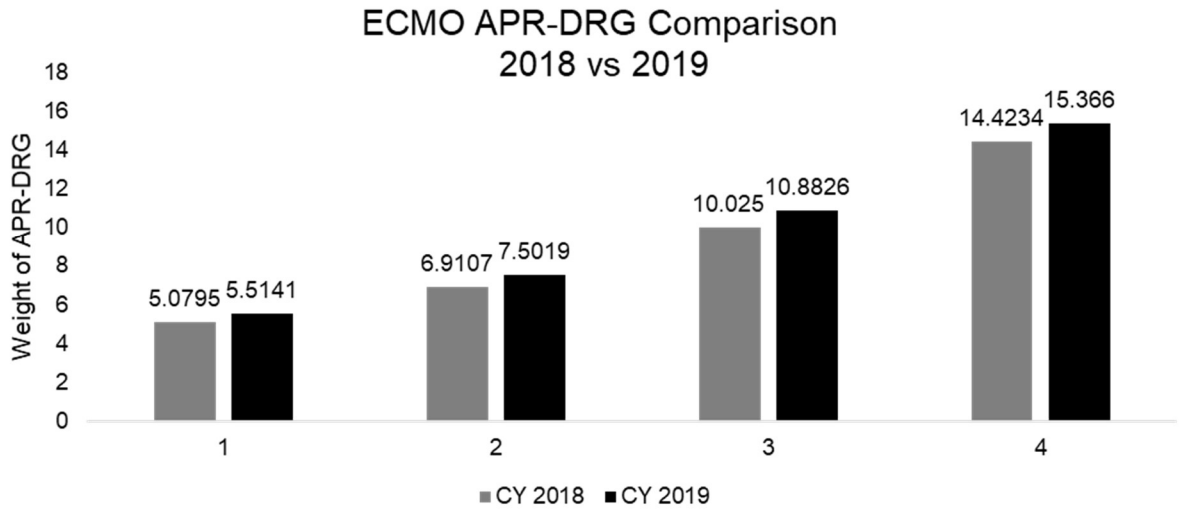


b. Peripheral ECMO Cases Are Currently Underpaid in FY 2019

Stakeholders expressed concerns that the MS-DRG assignments in the FY 2019 Final Rule resulted in underpayment for some ECMO cases, particularly for pediatric cases. We agree that the current MS-DRG assignments for ECMO results in underpayment for these procedures. However, pediatric patients were not impacted by the changes because these procedures are paid through the APR-DRG system and not the MS-DRG system. The APR-DRG rates are shown below and actually increased slightly as compared to prior year. In addition, femoral access (peripheral ECMO) is not available in infant/children due to vessel size. The most common procedure for ECMO would require an open chest/sternotomy.

[2] In prior rules, CMS has recognized when the claims data predated implementation of this coding guidance. In the FY19 IPPS Proposed Rule, CMS stated:

> "[W]e are aware that the AHA published Coding Clinic advice that clarified coding and reporting for certain external heart assist devices due to technology being approved for new indications. *The current claims data do not yet reflect that updated guidance.*" CMS, Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital and Prospective Payment System and Proposed Policy Changes and Fiscal Year 2019 Rates, etc., Proposed Rule, 83 Fed. Reg. 20164, 20185 (May 7, 2018) (emphasis added).



ECMO: APR-DRG 004 in CY 2018 and APR-DRG 009 in CY 2019

Prior to FY 2019, there was no code in the ICD-10 to distinguish between ECMO procedures with different types of support and varying invasiveness. Following the March 2018 C&M meeting, CMS adopted new codes for ECMO to distinguish between ECMO procedures requiring surgery to open the chest and those procedures that do not. In the FY 2019 Final Rule, CMS acknowledged the differences in invasiveness, patient populations, and resourcing between central and peripheral ECMO. CMS recognized that peripheral ECMO procedures "are less resource intensive compared to open ECMO procedures" and designated these codes as non-O.R. procedures.

As a result, CMS determined that it was not appropriate to assign all ECMO cases to MS-DRG 003, a higher paying MS-DRG. Instead, the agency assigned the new ICD-10 code for peripheral ECMO to MS-DRGs 207, 291, 296, and 870. In cases where a percutaneous external heart assist device is utilized in combination with peripheral ECMO, the case resulted in assignment to MS-DRG 215 because the percutaneous external heart assist device procedure is designated as an O.R. procedure.

The agency noted that it would re-evaluate these MS-DRG assignments once claims data became available. CMS proposed in the FY 2020 Proposed Rule to amend the MS-DRG assignments for ECMO and temporarily move all ECMO procedures to MS-DRG 003 without additional data to support this change.

c. CMS has Adopted New Codes for Peripheral ECMO Procedures

Since the Proposed Rule was published in early May, new ICD-10 codes were established to align payment for peripheral ECMO with the resource utilization attributable to those procedures. In May of this year, CMS published new codes to identify peripheral ECMO support during a procedure that is discontinued at the end of the procedure. These intraprocedural codes will allow CMS to distinguish between short-term and long-term ECMO procedures.

Current code(s) assignment	Code title	Effective October 1
5A1522F	Extracorporeal Oxygenation, Membrane, Central	2018
5A1522G	Extracorporeal Oxygenation, Membrane, Peripheral Veno-arterial	2018
5A1522H	Extracorporeal Oxygenation, Membrane, Peripheral Veno-venous	2018
5A15A2F	**Extracorporeal Oxygenation, Membrane, Central, Intraoperative**	**2019**
5A15A2G	**Extracorporeal Oxygenation, Membrane, Peripheral Veno-arterial, Intraoperative**	**2019**
5A15A2H	**Extracorporeal Oxygenation, Membrane, Peripheral Veno-venous, Intraoperative**	**2019**

Recommendations

a. Extend Hold Harmless For Other Heart Assist Devices (MS-DRG 215)

We recommend that CMS maintain the relative weight at the FY 2018 relative weight for any MS-DRG that was held-harmless last year and continues to face a 20% or greater cut from its FY 2019 relative weight. A hold harmless for FY 2020 is consistent with multiple stakeholders request for a multi-year transition in the FY 2018 and FY 2019 rulemakings to allow claims data for MS-DRG 215 to reflect coding changes.

In the FY 2019 Final Rule, CMS implemented a hold-harmless to protect patient access to critical heart assist devices in MS-DRG 215. During this past year, two major journal publications have been released showing dramatic improvements in survival from 50% to over 70% for patients using heart assist devices and a specific protocol.[3] The hold harmless preserved patient access to enable these innovations and publications. The FY 2019 Proposed Rule would have resulted in a two-year cut to MS-DRG 215 of over 40%. At the time, stakeholders requested a multi-year transition to ensure access to PVADs while the underlying data adjusted to recent coding changes. In the FY 2019 Final Rule, CMS recognized that the significant payment cut to MS-DRG 215 was an "outlier circumstance" and implemented a temporary one-time measure for an MS-DRG where the FY 2018 relative weight declined by 20% from the FY 2017 relative weight and the FY 2019 relative weight would have declined by more than 20% from the FY18 relative weight. For an MS-DRG that met this criterion, CMS used its authority to assign and update appropriate weighting factors under sections 1886(d)(4)(B) and (C) of the Act to hold the relative weight for these MS-DRGs at its FY 2018 relative weight.[4] This transition policy was critical to ensure continued access to life-saving heart assist pumps.

A hold harmless policy is consistent with CMS precedent in prior rulemakings. For example, CMS has previously "provided for transition periods when adopting changes that have significant payment implications, particularly large negative impacts."[5] Similarly, here, MS-DRG 215 faces a steep and

[3] *See* Basir, M. et. al. Improved outcomes Associated with the use of Shock Protocols: Updates from the National Cardiogenic Shock Initiative. *Catheter Cardiovasc Interv.* 2019;1-11; Tehrani, B. et. al. Implementation of a Cardiogenic Shock Team and Clinical Outcomes (INOVA-SHOCK Registry): Observational and Retrospective Study. JMIR Res Protoc 2018;7(6):e160 available at: http://www.researchprotocols.org/2018/6/e160/

[4] CMS, Medicare Program: Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and Long-Term Care Hospital Prospective Payment Systems and Proposed Policy Changes and Fiscal Year 2019 Rates, Final Rule, 83 Fed. Reg., 41144, 41273 (Aug. 17, 2018).

[5] *See* 79 Fed. Reg. 49854, 49957 (Aug. 22, 2014). For example, in FY2015, CMS adopted a "3-year hold harmless transitional wage index adjustment" in the FY2015 IPPS to "alleviate the decreased payments" for hospitals formerly located in urban counties that became rural under new OMB delineations. *Id.* CMS determined that the 3-year hold harmless transition was

abrupt reduction in payment rate. A hold-harmless transition will stabilize provider expectations as data begins to reflect the new AHA coding guidance. Furthermore, CMS has concluded in prior rulemakings that it is "prudent" to delay implementation of a proposed rate change when more current data could limit cuts to providers.[6] A delay is appropriate here where more current data will reflect new coding guidance and subsequently limit cuts to providers.[7]

b. MS-DRG Assignment for New ECMO Codes to Increase Payment for ECMO and Avoid a Tiered Payment

Instead of temporarily moving short-term ECMO cases to MS-DRG 003, we recommend that CMS adopt a permanent solution to ECMO coding that reflects the resource utilization for different ECMO procedures and avoids a tiered payment system for heart assist devices. The newly issued codes and newly released IPSAF data for peripheral VA and VV ECMO offer a permanent solution for ECMO payment that was not available when the Proposed Rule was published.

While there is only one quarter of IPSAF data from FY 2019 to review, we agree that patients who have an open chest insertion of ECMO and are supported by it for more than 96 hours have a resource consumption beyond those who require short-term temporary support.

We recommend that CMS assign the new non-OR peripheral VV and VA ECMO codes to MS-DRG 215. MS-DRG 215 is the primary MS-DRG for other peripheral heart assist pumps with similar patient populations. Assigning the new codes for peripheral ECMO to MS-DRG 215 will align all peripheral heart assist devices and eliminate inappropriate incentives for off-label therapy. Assigning the new peripheral ECMO codes to MS-DRG 215 will also have the added benefit of stabilizing the relative weight for that MS-DRG. These code assignments would offer a permanent solution for accurate payment for heart assist devices.

If CMS finalizes the Proposed Rule by assigning peripheral ECMO patients to MS-DRG 003 it will make the payment rate for peripheral ECMO out-of-line with payment for similar procedures for similar patient populations. Patients receiving peripheral ECMO do not share clinical similarities to other patients in MS-DRG 003 and the costs of these procedures.

Assigning the new non-OR peripheral VA and VV ECMO codes to MS-DRG 215 is also supported by recently released data. SAF data on ECMO from Q1 2019 provides new information on the weight differential between peripheral and central ECMO procedures. This data confirms the prior conclusions

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appropriate because CMS expected this group of hospitals to "experience a steeper and more abrupt reduction in their wage index due to the labor market revisions compared to other hospitals." *Id.*

[6] In the FY2010 IPPS Final Rule, CMS delayed adoption of a documentation and coding adjustment to hospital-specific rates until FY2011. 74 Fed. Reg. 43754, 43775 (Aug. 27, 2009). CMS had originally indicated in the FY2009 IPPS rule that CMS would make adjustments to the hospital-specific rate in the FY2010 rulemaking if the FY2008 claims data for hospitals paid based on the hospital-specific rate demonstrated a significant increase in payments resulting from documentation and coding changes that did not reflect real increases in patients' severity of illness. The 2008 data showed such a change unrelated to real changes in case-mix. Although CMS proposed to make a negative 2.5% adjustment in the FY2010 proposed rule, the agency decided to delay implementation of the adjustment in the Final Rule so that it could analyze additional claims data. CMS decided to wait to fully review the FY2009 claims data, to determine if it could potentially lessen the anticipated cumulative adjustments. CMS concluded that "it would be more prudent to delay implementation of the documentation and coding adjustment to allow for a more complete analysis of FY2009 claims data for hospitals receiving hospital-specific rates."

[7] CMS could also implement this policy through its authority under Section 1886(d)(5)(I)(i), which allows CMS to "provide by regulation for such other exceptions and adjustments to such payment amounts under [IPPS] as the Secretary deems appropriate."

by CMS's clinical advisors that central ECMO is more resource intensive compared to peripheral ECMO procedures.[8]

Code	Procedure	FY19 Q1 SAF Count	FY19 Q1 SAF Mean Weight
5A1522F	Central ECMO	134	18.4259
5A1522G	Perc VA (Cardiac) ECMO	418	10.0506
5A1522H	Perc VV (Respiratory) ECMO	164	9.3960

WATSON POLICY ANALYSIS

*weight is for the DRG in 2019 as billed

CMS has previously assigned new codes that were released after the Proposed Rule was released. For example, in evaluating the new ECMO codes that were established in 2018, CMS, in the FY 2019 Final Rule, evaluated the predecessor procedure code assignments for the new ECMO procedure codes. The agency stated that in the absence of volume, length of stay, and cost data, CMS will consider the specific services, procedure, or treatment being described by new procedure codes, the indications, treatment, difficulty, and resources used.

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We appreciate CMS's consideration of our comments on the proposed cuts in relative weight for MS-DRG 215 and the appropriate coding and payment for peripheral ECMO. To discuss any of the issues raised in this comment letter, please contact me at sbunk@abiomed.com.

Respectfully submitted,

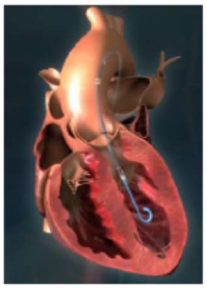
Stacey Bunk, MS, CPC, CCC, FABC
Director, Reimbursement & Healthcare Economics
ABIOMED, Inc

[8] 83 Fed. Reg. 41168

Appendix

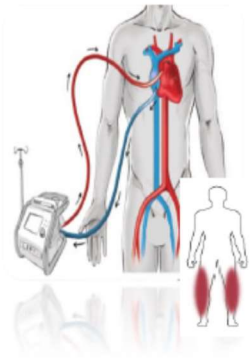
HEART PUMP TECHNOLOGIES – SHORT-TERM VS LONGER-TERM / OPEN

PVAD (Impella)



MS-DRG 215

Perc ECMO

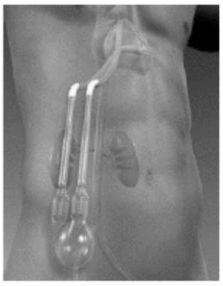


Proposed: MS-DRG 3

Recommend: MS-DRG 215

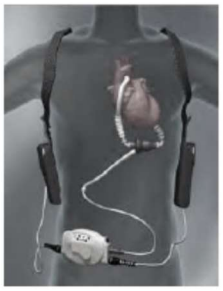
FY2019: MS-DRG 291, 296, 207, 870

External LVAD



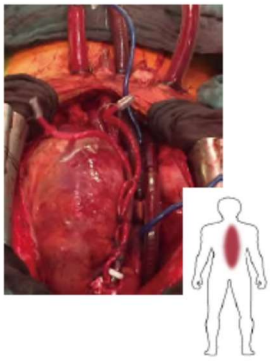
MS-DRG 1 or 2

Implantable LVAD



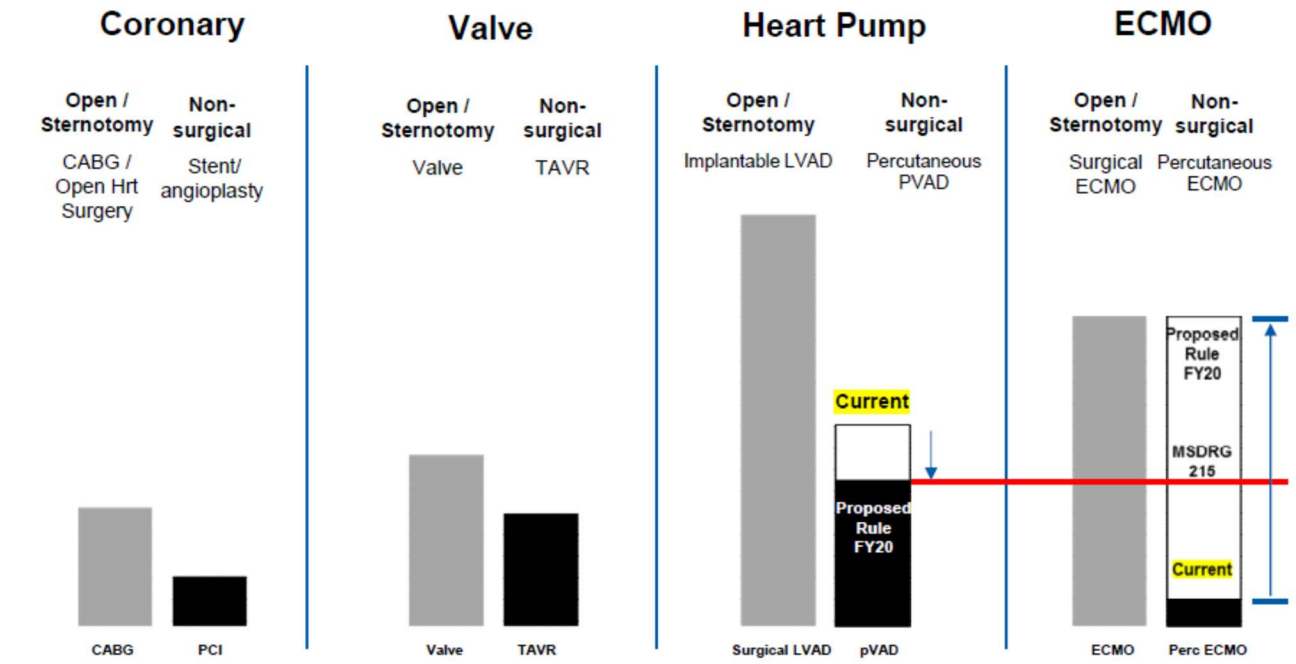
MS-DRG 1 or 2

Open Chest/ ECMO



MS-DRG 3

OPEN CHEST VS. PERCUTANEOUS / SHORT –TERM DRGS



FY19 Sample DRG rate estimates
Using MCCs for all comparative data

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